(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(*a*) The bacitracin used in making the batch: 10 packages, each containing approximately 1.0 gram.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each containing 1.0 gram.

(*c*) The batch: A minimum of 12 immediate containers.

(b) *Tests and methods of assay.* The container must remain inverted throughout the sampling procedure. Freeze the container overnight at −70 °C. Remove from the freezer and puncture the container to allow the propellant to dissipate. Open the container, mix well, and proceed as described in paragraphs (b) (1) and (2) of this section.

(1) *Potency*—(i) *Bacitracin content.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the sample from the container into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 20 to 25 milliliters of 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1), and shake well. Allow the layers to separate. Remove the buffer layer and repeat the extraction procedure with each of three more 20- to 25-milliliter quantities of solution 1. Combine the buffer extractives in a suitable volumetric flask and dilute to volume with solution 1. Remove an aliquot, add sufficient hydrochloric acid so that the amount of acid in the final solution will be the same as in the reference concentration of the working standard, and further dilute with solution 1 to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated).

(ii) *Polymyxin B content.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately weighed portion of the sample from the container into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 20 to 25 milliliters of 10 percent potassium phosphate buffer, pH 6.0 (solution 6), and shake well. Allow the layers to separate. Remove the buffer layer and repeat the extraction procedure with each of three more 20- to 25-milliliter quantities of solution 6. Combine the buffer extractives in a suitable volumetric flask and dilute to volume with solution 6. Remove an aliquot and further dilute with solution 6 to the reference concentration of 10 units of polymyxin B per milliliter (estimated).

(2) *Moisture.* Proceed as directed § 436.201 of this chapter, using the titration procedure and calculation in paragraph (e)(3) of that section and 1- to 2-milliliter portions of the sample from the container.

[51 FR 35212, Oct. 2, 1986, as amended at 55 FR 9722, Mar. 15, 1990; 55 FR 11584, Mar. 29, 1990]

§ 448.513 Bacitracin zinc dermatologic dossage forms.

§ 448.513a Bacitracin zinc-polymyxin B sulfate ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Bacitracin zinc-polymyxin B sulfate ointment contains bacitracin zinc and polymyxin B sulfate in a suitable and harmless ointment base. It may contain a suitable local anesthetic. Each gram contains 500 units of bacitracin and 10,000 units of polymyxin B. Its bacitracin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of bacitracin that it is represented to contain. Its polymyxin B content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain. Its moisture content is not more than 0.5 percent. The bacitracin zinc used conforms to the standards prescribed by § 448.13(a)(1). The polymyxin B sulfate used conforms to the standards prescribed by § 448.30(a)(1).

(2) *Labeling.* (i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.